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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,293	11/17/2003	Stephen P. Massia	112624.00028 CIP	8809

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,293	MASSIA ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-101* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-101 are pending and require restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20, 25-46 and 101, drawn to bioconjugates, a kit comprising the bioconjugates and therapeutic replacement fluids comprising the bioconjugates, classified in class 514, subclass 2.

II. Claims 21-22, drawn to nucleic acids encoding the peptide portions of the bioconjugates having one or more of the peptides of SEQ ID NOs: 1-202, classified in class 536, subclass 23.4.

III. Claim 23, drawn to peptides of SEQ ID NOs: 1-112 having an additional N and/or C terminal cysteine, classified in class 530, subclass 300.

IV. Claim 24, drawn to the nucleic acids encoding the peptides of Group III, classified in class 536, subclass 23.4.

V. Claim 47, drawn to a biointerface formed on mammalian tissue comprising a plurality of the conjugates of Group I bound to a plurality of ligands on said tissue, classified in class 514, subclass 2.

VI. Claims 48-55, drawn to methods of preparing bioconjugates, classified in class 530, subclass 333.

VII. Claim 56, drawn to a method for preventing adhesion of a mobile cell to a cell immobilized on a substrate, classified in class 427, subclass 2.1.

VIII. Claims 57-100, drawn to a method of blocking pathological reactions triggered by cellular interactions in a living tissue, classified in class 514, subclass 2.

The inventions are independent or distinct, each from the other because of the following reasons:

Inventions I and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)).

In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the products of Group I do not require the plurality of ligands of the tissue. As evidenced by the claims themselves, the subcombination has separate utility such as preventing adhesion of mobile cells to immobilized cells and blocking pathological reactions triggered by cellular interactions in living tissue. Additionally, the bioconjugates of Group I can be used as, e.g., antiinflammatories.

Inventions I and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case the process is not limited in scope to making only the bioconjugate compounds of Group I and can be used to make a materially different product, e.g., PEGylated substance P.

Inventions I and VII and I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h).

In the instant case one could prevent adhesion of a mobile cell to a cell immobilized on a substrate with heparin and one could block pathological reactions in living tissue by administration of an anti-inflammatory, e.g. naproxen.

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

In the instant case, the different inventions have different structures, Group I being bioconjugates, Group II being nucleic acids encoding the peptide portion of Group I, and Group III being peptides with additional N and/or C terminal cysteine(s) and Group IV being the nucleic acids encoding the peptides of Group III. The nucleic acids encoding Group III do not encode the peptide portion of the bioconjugates, as the bioconjugates do not have an additional N and/or C terminal cysteine. The peptide portion of the bioconjugates do not have an addition N and/or C terminal cysteine.

Inventions II-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

In the instant case, the biointerface of Group V does not require or use the products of inventions II-IV, and the methods of Groups VI-VIII do not specifically require the use of the products of any of Groups II-V. Further, the different methods of Groups VI-VIII are not disclosed as capable of use together, with the methods having different steps and different desired outcomes, such that in practicing one method, one would not be practicing another. For example, in preventing adhesion of a mobile cell to a cell immobilized on a substrate one would not necessarily be blocking pathological reactions triggered by cellular interactions in a living tissue, nor would one be preparing bioconjugates in either methods.

If Applicant elects either Group III or IV, Applicant is required to elect a single peptide as the elected invention. The peptides, or encoding nucleic acids, were not found to share a

significant structural core from which a meaningful coextensive search could be conducted, thus a separate and distinct search, as well as examination, of each peptide sequence, or encoding nucleic acid, is required. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each peptide, or encoding nucleic acid, is assumed to be a patentably distinct invention.**

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Additionally, the compounds of the instant application are distinct, absent evidence to the contrary, and would require a unique search strategy. The search for the distinct compounds is conducted based on their chemical structure. Therefore, the search of one chemical structure would not necessarily lead to the discovery of another structure, nor would it necessarily lead to the discovery of methods of using and/or making.

Because these inventions are independent or distinct for the reasons given above, the inventions require a different field of search (see MPEP § 808.02) and the search for one invention would not necessarily lead to the discovery of another invention, restriction for examination purposes as indicated is proper, and to not restrict would be an undue burden on the Examiner.

Claims 1-20 and 25-100 are generic to a myriad of patentably distinct species of 'bioconjugates', too numerous to recite individually, comprising: one or more peptides 'capable of binding specifically to a ligand expressed on a cell surface' and 'a hydrophilic polymer',

including one or more of the peptides of SEQ ID NOs: 1-202 of claim 8 and the polymer poly/oligosaccharides of claim 31.

Claims 21-22 are generic to a myriad of patentably distinct species of the nucleic acid encoding the peptide portion of the peptides comprising 1 or more of SEQ ID NOs:1-202.

The species are independent or distinct because the structures of each compound are such that the search of one would not necessarily lead to the discovery of another. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder Practice

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

The prior art made of record on the attached PTO-892 and not relied upon in any rejection is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ADK/
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